

3.0 510(k) SummaryPage 1 of 1

Sponsor: Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Contact: Amnon Talmor
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-6604

Device Name: Synthes (USA) Sternal Fixation System—Line Extension

Classification: Class II per 21 CFR §888.3040: Screw, Fixation, Bone, Metallic

Predicate Devices: Synthes (USA) Sternal Fixation System
Synthes (USA) Sterile Sternal Fixation System

Device Description: The Synthes (USA) Sternal Fixation System consists of machined titanium plates, a quick-release pin and 3.0 mm locking screws. The plates utilize screw fixation to create the construct.

Intended Use: The Synthes (USA) Sternum Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Substantial Equivalence: Documentation is provided that demonstrates the Synthes (USA) Sternal Fixation System - modification to be substantially equivalent to other legally marketed devices such as: Synthes (USA) Sternal Fixation System



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2008

Synthes (USA)
% Mr. Amnon Talmor
1301 Goshen Parkway
West Chester, PA 19380

Re: K081700
Trade/Device Name: Synthes (USA) Sternal Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
~~Regulatory Class: Class II~~
Product Code: HWC
Dated: June 12, 2008
Received: June 17, 2008

Dear Mr. Talmor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and ~~adulteration~~.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Amnon Talmor

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. ~~You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.~~

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



2.0

Indications for Use

510(k) Number (if known): K081700

Device Name: Synthes (USA) Sternal Fixation System

Indications for Use: The Synthes (USA) Sternal Fixation System is intended for use in primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K081700